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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC.,	)	
	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-cv-05921
	)	
MICRO LABS USA, INC. and MICRO LABS LIMITED,	)	
	)	
	)	
Defendants.	)	
	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Micro Labs USA, Inc. and Micro Labs Limited (collectively "Micro Labs"). This action arises out of Micro Labs' submission of Abbreviated New Drug Application ("ANDA") No. 219182 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of NEXLETOL® prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584 (collectively, the "Asserted Patents").

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

3. Upon information and belief, Defendant Micro Labs USA, Inc. ("Micro Labs USA") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 220 Davidson Avenue, Suite 402, Somerset, NJ 08873.

4. Upon information and belief, Micro Labs USA is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs).

5. Upon information and belief, Micro Labs USA directly or through its affiliates, markets and sells drug products throughout the United States, including in the state of New Jersey.

6. Upon information and belief, Defendant Micro Labs Limited ("MLL") is a corporation organized and existing under the laws of India, having a place of business at 31, Race Course Road, Bangalore, India 560 001.

7. Upon information and belief, MLL is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

8. Upon information and belief, MLL directly or through its affiliates, including Micro Labs USA, markets and sells drug products throughout the United States, including in the state of New Jersey.

9. Upon information and belief, Micro Labs USA is a wholly owned subsidiary of MLL.

10. Upon information and belief, MLL directs or controls the operations, management, and activities of Micro Labs USA in the United States.

11. Upon information and belief, MLL and Micro Labs USA are agents of each other and/or operate in concert as integrated parts of the same business group.

12. On information and belief, MLL and Micro Labs USA work together with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products.

13. Upon information and belief, MLL and Micro Labs USA acted in concert to prepare and submit ANDA No. 219182 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Micro Labs ANDA Product") prior to the expiration of the Asserted Patents.

14. On information and belief, MLL and Micro Labs USA acted in concert to develop and seek regulatory approval from the FDA to market and sell the Micro Labs ANDA Product throughout the United States, including in New Jersey.

15. On information and belief, MLL and Micro Labs USA intend to act collaboratively to obtain approval for Micro Labs' ANDA No 219182, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Micro Labs ANDA Product in the United States, including in New Jersey.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Micro Labs USA because, on information and belief, Micro Labs USA is a company organized and existing under the laws of the state of

New Jersey, is qualified to do business in New Jersey, and has its principal place of business in New Jersey.

18. In view of the foregoing, Micro Labs USA is subject to general personal jurisdiction in New Jersey.

19. This Court has personal jurisdiction over MLL because MLL, in concert with its subsidiary Micro Labs USA, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing ANDA No. 219182 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c), including in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, on information and belief, following approval of ANDA No. 219182, MLL, in concert with its subsidiary Micro Labs USA, will make, use, import, sell, and/or offer for sale the Micro Labs ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

20. This Court also has personal jurisdiction over MLL because, among other things, this action arises from MLL's, and its subsidiary Micro Labs USA's, actions directed toward New Jersey, and because, upon information and belief, MLL, and its subsidiary Micro Labs USA, have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by marketing pharmaceutical products in New Jersey. MLL has therefore purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

21. In addition, this Court has personal jurisdiction over MLL because, among other things, on information and belief, (1) MLL and its subsidiary Micro Labs USA filed Micro Labs' ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or

offer for sale of the Micro Labs ANDA Product in the United States, including in New Jersey, and (2) upon approval of Micro Labs' ANDA, MLL and its subsidiary Micro Labs USA will market, distribute, offer for sale, sell, and/or import the Micro Labs ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Micro Labs ANDA Product in New Jersey. On information and belief, upon approval of Micro Labs' ANDA, the Micro Labs ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

22. This Court also has personal jurisdiction over Micro Labs USA and MLL because both Micro Labs USA and MLL regularly engage in patent litigation in this forum, including in *Aerie Pharmaceuticals, Inc. v. Micro Labs Ltd.*, C.A. No. 22-cv-01365 (D.N.J. filed Mar. 14, 2022), *Allergan Sales, LLC v. Micro Labs Ltd.*, C.A. No. 19-cv-09759 (D.N.J. filed Apr. 12, 2019), *Takeda GmbH v. Micro Labs USA, Inc.*, CA. No. 15-cv-07921 (D.N.J. filed Nov. 5, 2015).

23. Based on the foregoing systematic and continuous contacts with New Jersey, MLL is subject to specific personal jurisdiction in New Jersey.

24. On information and belief, MLL's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent MLL denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court has personal jurisdiction over MLL pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

25. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Micro Labs to litigate this action in this Court, and Micro Labs is subject to personal jurisdiction in New Jersey.

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

27. Venue is proper in this Court as to Defendant Micro Labs USA under 28 U.S.C. § 1400(b) because it is a company organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this Court, as set forth above, has committed acts of infringement, and, upon information and belief, will commit further acts of infringement in New Jersey.

28. Venue is also proper in this Court for Defendant Micro Labs USA because it has a regular and established place of business in New Jersey at least because, upon information and belief, it (1) is organized under the laws of New Jersey; (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (3) has acted in concert with MLL to prepare and file its ANDA, and to seek approval from the FDA to market and sell the Micro Labs ANDA Product in the United States, including in New Jersey.

29. Venue is proper in this Court as to MLL under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, MLL is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

30. Venue is also proper in this Court for Defendant MLL because it has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has

sought approval from the FDA to market and sell Defendants' proposed generic NEXLETOL® product in New Jersey; (2) acted in concert with Micro Labs USA in New Jersey to prepare and file its ANDA; (3) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (4) has a New Jersey subsidiary, Micro Labs USA, through which it will make, use, import, sell, and/or offer for sale Defendants' proposed generic NEXLETOL® product in the United States, including in New Jersey.

THE PATENTS-IN-SUIT

31. U.S. Patent No. 11,760,714 ("the '714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit A."

32. Esperion is the assignee of, and holds all rights, title, and interest in the '714 patent.

33. The '714 Patent currently expires on June 19, 2040.

34. U.S. Patent No. 11,613,511 ("the '511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit B."

35. Esperion is the assignee of, and holds all rights, title, and interest in the '511 patent.

36. The '511 Patent currently expires on June 19, 2040.

37. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit C."

38. Esperion is the assignee of, and holds all rights, title, and interest in the '584 Patent.

39. The '584 Patent currently expires on June 19, 2040.

40. All claims of the '714, '511, and '584 Patents are valid, enforceable, and not expired.

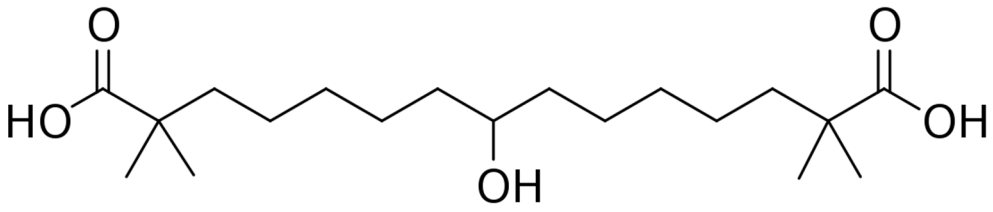
ESPERION'S NEXLETOL PRODUCT

41. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

42. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

43. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

44. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



45. The claims of the Asserted Patents cover NEXLETOL®.

46. The Asserted Patents have been listed in connection with NEXLETOL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

MICRO LABS' ANDA PRODUCT

47. By letter dated March 25, 2024, and received by Esperion via Federal Express no earlier than on March 26, 2024 (the "First Notice Letter"), Micro Labs notified Esperion that Micro Labs had submitted ANDA No. 219182 to the FDA for a generic version of NEXLETOL®.

48. The First Notice Letter states that Micro Labs seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Micro Labs ANDA product before the expiration of the '714 and '511 Patents. Upon information and belief, Micro Labs intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Micro Labs ANDA product promptly upon receiving FDA approval to do so.

49. By submitting ANDA No. 219182, Micro Labs has represented to the FDA that the Micro Labs ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

50. In the First Notice Letter, Micro Labs stated that ANDA No. 219182 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Micro Labs also contended that the '714 and '511 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Micro Labs' ANDA Product.

51. Upon information and belief, Micro Labs had knowledge of the '714 and '511 Patents when it submitted ANDA No. 219182 to the FDA.

52. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product immediately and

imminently upon approval of ANDA No. 219182 and prior to expiration of the '714 and '511 Patents.

53. On or about April 26, 2024, pursuant to an Offer of Confidential Access set forth in the First Notice Letter, Micro Labs produced portions of its ANDA No. 219182 to Esperion. Micro Labs refused to produce the entirety of ANDA No. 219182 to Esperion and refused to provide samples of its ANDA Product or components.

54. Esperion filed the original complaint in this action on May 8, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First Notice Letter.

55. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 patent.

56. On or about April 9, 2024, and within thirty days of issuance of the '584 patent, Esperion submitted Form 3542 identifying the '584 patent for listing in the Orange Book for NEXLETOL®.

57. On information and belief, at some point on or after April 9, 2024, during the pendency of Micro Labs' ANDA, Micro Labs provided to the FDA a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

58. By letter dated June 5, 2024, and received by Esperion via email on June 5, 2024, and via Federal Express no earlier than on June 6, 2024 (the "Second Notice Letter"), Micro Labs sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. In the Second Notice Letter, Micro Labs contended that the '584 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the Micro Labs ANDA Product.

59. Upon information and belief, Micro Labs had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 5, 2024.

60. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product immediately and imminently upon approval of ANDA No. 219182 and prior to expiration of the '584 Patent.

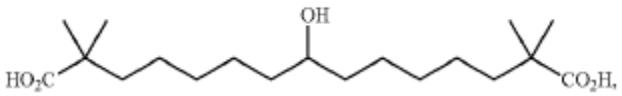
61. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second Notice Letter and prior to Micro Labs' answer to the original complaint filed May 8, 2024.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

62. Esperion incorporates each of the preceding paragraphs 1-61 as if fully set forth herein.

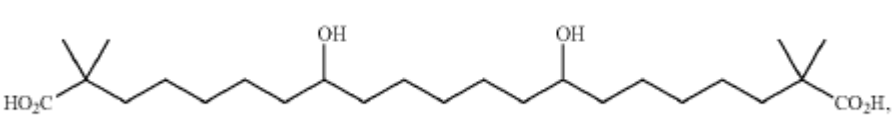
63. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

(VI)



and a pharmaceutically acceptable excipient.

64. Micro Labs' submission of ANDA No. 219182 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA

Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

65. Micro Labs' commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product prior to expiration of the '714 Patent, and Micro Labs' inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

66. Upon information and belief, upon FDA approval of ANDA No. 219182, Micro Labs intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, unless enjoined by the Court.

67. Upon information and belief, by virtue of their listing in the Orange Book and its First Notice Letter, Micro Labs has knowledge of the '714 Patent and knowledge that its Micro Labs ANDA Product will infringe the '714 Patent.

68. Upon information and belief, Micro Labs intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219182 is approved by marketing the Micro Labs ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

69. Upon information and belief, Micro Labs intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219182 is approved, unless enjoined by the Court, because Micro Labs knows that the Micro Labs ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Micro Labs ANDA Product is not suitable for substantial noninfringing use.

70. Micro Labs infringement is imminent because, among other things, Micro Labs has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '714 Patent.

71. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

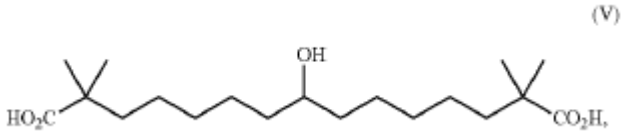
72. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Micro Labs' making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

73. Unless Micro Labs is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

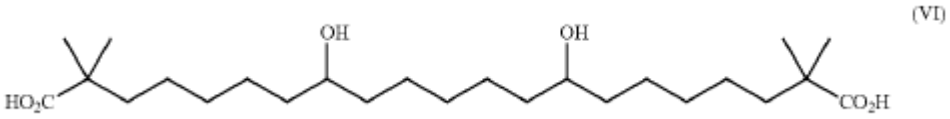
74. Esperion incorporates each of the preceding paragraphs 1-73 as if fully set forth herein.

75. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than

99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

76. Micro Labs' submission of ANDA No. 219182 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

77. Micro Labs' commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product prior to expiration of the '511 Patent, and Micro Labs' inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

78. Upon information and belief, upon FDA approval of ANDA No. 219182, Micro Labs intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, unless enjoined by the Court.

79. Upon information and belief, by virtue of their listing in the Orange Book and its First Notice Letter, Micro Labs has knowledge of the '511 Patent and knowledge that its Micro Labs ANDA Product will infringe the '511 Patent.

80. Upon information and belief, Micro Labs intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219182 is approved by marketing the Micro Labs ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

81. Upon information and belief, Micro Labs intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219182 is approved, unless enjoined by the Court, because Micro Labs knows that the Micro Labs ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Micro Labs ANDA Product is not suitable for substantial noninfringing use.

82. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

83. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Micro Labs' making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

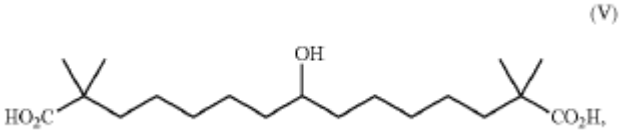
84. Unless Micro Labs is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,926,584

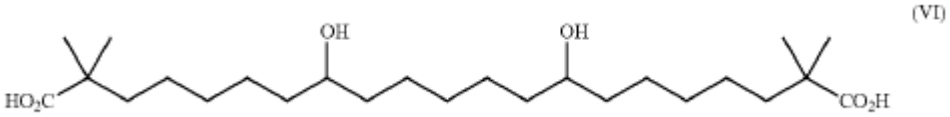
85. Esperion incorporates each of the preceding paragraphs 1-84 as if fully set forth herein.

86. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a

therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



87. Micro Labs' submission of ANDA No. 219182 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

88. Micro Labs' commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product prior to expiration of the '584 Patent, and Micro Labs' inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

89. Upon information and belief, upon FDA approval of Micro Labs' ANDA No. 219182, Micro Labs will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Micro Labs ANDA Product in the United States and/or importing said product

into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

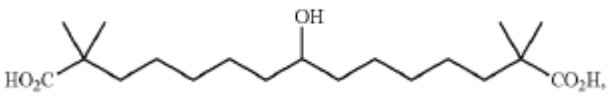
90. Upon information and belief, Micro Labs specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219182 is approved by marketing the Micro Labs ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

91. Upon information and belief, Micro Labs' ANDA No. 219182 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Micro Labs ANDA Product.

92. Upon information and belief, upon FDA approval of ANDA No. 219182, Micro Labs intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, unless enjoined by the Court, and the Micro Labs ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

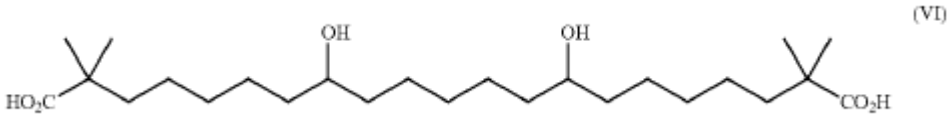
93. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than

99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

94. Upon information and belief, the use of the Micro Labs ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the ’584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

95. Upon information and belief, by virtue of its listing in the Orange Book and identification in Micro Labs’ Second Notice Letter, Micro Labs has knowledge of the ’584 Patent and knowledge that its Micro Labs ANDA Product will infringe the ’584 Patent.

96. On information and belief, Micro Labs is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Micro Labs ANDA Product at least according to Micro Labs’ proposed package insert and, therefore, will directly infringe at least claim 1 of the ’584 Patent.

97. Upon information and belief, Micro Labs intends to, and will, contribute to infringement of at least claim 1 of the ’584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219182 is approved, unless enjoined by the Court, because Micro Labs knows that the Micro Labs ANDA Product is especially made or adapted for use in infringing the ’584 Patent, and that the Micro Labs ANDA Product is not suitable for substantial noninfringing use.

98. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the ’584 Patent.

99. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Micro Labs' making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

100. Unless Micro Labs is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Esperion asks that this Court grant the following relief:

101. A judgment that the claims of the Asserted Patents are infringed by Micro Labs' submission of ANDA No. 219182 under 35 U.S.C. § 271(e)(2)(A);

102. A declaratory judgment that Micro Labs' manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Micro Labs ANDA Product prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

103. A judgment that the Asserted Patents are not invalid or unenforceable;

104. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Micro Labs ANDA No. 219182 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

105. An Order permanently enjoining Micro Labs, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Micro Labs, from making, using, offering to sell, selling, or importing the Micro Labs ANDA

Product until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

106. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Micro Labs engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Micro Labs ANDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

107. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

108. Such further and other relief as this Court deems proper and just.

Dated: June 21, 2024

/s/ *Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following action:

- *Esperion Therapeutics, Inc. v. Renata Ltd.*, Civil Action No. 2:24-cv-06017-JXN-CLW
- *Esperion Therapeutics, Inc. v. Accord Healthcare Inc., et al.*, Civil Action No. 2:24-cv-06224-JXN-CLW
- *Esperion Therapeutics, Inc. v. Alkem Labs., et al.*, Civil Action No. 2:24- cv-06263-JXN-CLW
- *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, Civil Action No. 2:24- cv-06348-JXN-CLW
- *Esperion Therapeutics, Inc. v. MSN Pharmaceuticals Inc., et al.*, Civil Action No. 2:24-cv-06386-JXN-CLW
- *Esperion Therapeutics, Inc. v. Sandoz Inc.*, Civil Action No. 2:24-cv-06387-JXN-CLW
- *Esperion Therapeutics, Inc. v. Hetero USA Inc.*, Civil Action No. 2:24-cv-06389-JXN-CLW
- *Esperion Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 2:24-cv-06391-JXN-CLW

Dated: June 21, 2024

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: June 21, 2024

By: */s/ Liza M. Walsh*

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